# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/IL05/000304

International filing date: 17 March 2005 (17.03.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/570,469
Filing date: 13 May 2004 (13.05.2004)

Date of receipt at the International Bureau: 06 June 2005 (06.06.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

PA 1313015

# THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

**UNITED STATES DEPARTMENT OF COMMERCE**

**United States Patent and Trademark Office**

**April 29, 2005**

**THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.**

**APPLICATION NUMBER:** *60/570,469*
**FILING DATE:** *May 13, 2004*

**By Authority of the**
**COMMISSIONER OF PATENTS AND TRADEMARKS**

T. Lawrence

**T. LAWRENCE**
**Certifying Officer**

166698 U.S.PTO

PTO/SB/16 (01-04)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

## INVENTOR(S)

| Given Name (first and middle [if any]) | Family Name or Surname | Residence (City and either State or Foreign Country) |
|---|---|---|
| ELAN | ZIV MD | RAMAT GAN ISRAEL |

*Additional inventors are being named on the* _____ *separately numbered sheets attached hereto*

## TITLE OF THE INVENTION (500 characters max)

A FLEXIBLE MID-URETHRAL SUPPORT DEVICE FOR THE TREATMENT AND PREVENTION OF URINARY INCONTINENCE IN FEMALES

*Direct all correspondence to:* **CORRESPONDENCE ADDRESS**

☐ Customer Number:

OR

| | | | | | |
|---|---|---|---|---|---|
| ☐ Firm or Individual Name | ELAN ZIV MD | | | | |
| Address | 8 HAILANOT ST | | | | |
| Address | | | | | |
| City | RAMAT GAN | State | | Zip | 52648 |
| Country | ISRAEL | Telephone | | Fax + | 972-3-7369263 |

2264 U.S.PTO 60/570469 051304

## ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* 7 ☐ CD(s), Number _____

☑ Drawing(s) *Number of Sheets* 6 ☐ Other (specify) _____

☐ Application Data Sheet. See 37 CFR 1.76

## METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.

☑ A check or money order is enclosed to cover the filing fees.

☐ The Director is herby authorized to charge filing fees or credit any overpayment to Deposit Account Number: _____

☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE Amount ($): $80

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____



*Respectfully submitted,*

SIGNATURE /s/

TYPED or PRINTED NAME Dr. ELAN ZIV MD

TELEPHONE +972-52-3569928

Date 30.4.04

REGISTRATION NO. _____ *(if appropriate)*

Docket Number: _____

***USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT***



***If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.***

16698

PTO/SB/17 (10-03)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

S.PTO

# FEE TRANSMITTAL for FY 2004

*Effective 10/01/2003. Patent fees are subject to annual revision.*

☑ Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** ($) 80

| Complete if Known | |
|---|---|
| Application Number | |
| Filing Date | ~~MARCH 15, 2004~~ May 11 2004 |
| First Named Inventor | Dr Elan Ziv |
| Examiner Name | |
| Art Unit | |
| Attorney Docket No. | |

## METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☑ Money Order ☐ Other ☐ None

☐ Deposit Account:

Deposit Account Number
Deposit Account Name

The Director is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☐ Credit any overpayments

☐ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1001 | 770 | 2001 | 385 | Utility filing fee | |
| 1002 | 340 | 2002 | 170 | Design filing fee | |
| 1003 | 530 | 2003 | 265 | Plant filing fee | |
| 1004 | 770 | 2004 | 385 | Reissue filing fee | |
| 1005 | 160 | 2005 | 80 | Provisional filing fee | 80 |

SUBTOTAL (1) ($) 80

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| | Extra Claims | | Fee from below | Fee Paid |
|---|---|---|---|---|
| Total Claims | | -20** = | X | = |
| Independent Claims | | - 3** = | X | = |
| Multiple Dependent | | | | = |

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 1202 | 18 | 2202 | 9 | Claims in excess of 20 |
| 1201 | 86 | 2201 | 43 | Independent claims in excess of 3 |
| 1203 | 290 | 2203 | 145 | Multiple dependent claim, if not paid |
| 1204 | 86 | 2204 | 43 | ** Reissue independent claims over original patent |
| 1205 | 18 | 2205 | 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 1051 | 130 | 2051 | 65 | Surcharge - late filing fee or oath | |
| 1052 | 50 | 2052 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 | 130 | 1053 | 130 | Non-English specification | |
| 1812 | 2,520 | 1812 | 2,520 | For filing a request for ex *parte* reexamination | |
| 1804 | 920* | 1804 | 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 | 1,840* | 1805 | 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 | 110 | 2251 | 55 | Extension for reply within first month | |
| 1252 | 420 | 2252 | 210 | Extension for reply within second month | |
| 1253 | 950 | 2253 | 475 | Extension for reply within third month | |
| 1254 | 1,480 | 2254 | 740 | Extension for reply within fourth month | |
| 1255 | 2,010 | 2255 | 1,005 | Extension for reply within fifth month | |
| 1401 | 330 | 2401 | 165 | Notice of Appeal | |
| 1402 | 330 | 2402 | 165 | Filing a brief in support of an appeal | |
| 1403 | 290 | 2403 | 145 | Request for oral hearing | |
| 1451 | 1,510 | 1451 | 1,510 | Petition to institute a public use proceeding | |
| 1452 | 110 | 2452 | 55 | Petition to revive - unavoidable | |
| 1453 | 1,330 | 2453 | 665 | Petition to revive - unintentional | |
| 1501 | 1,330 | 2501 | 665 | Utility issue fee (or reissue) | |
| 1502 | 480 | 2502 | 240 | Design issue fee | |
| 1503 | 640 | 2503 | 320 | Plant issue fee | |
| 1460 | 130 | 1460 | 130 | Petitions to the Commissioner | |
| 1807 | 50 | 1807 | 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 | 180 | 1806 | 180 | Submission of Information Disclosure Stmt | |
| 8021 | 40 | 8021 | 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 | 770 | 2809 | 385 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 | 770 | 2810 | 385 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 | 770 | 2801 | 385 | Request for Continued Examination (RCE) | |
| 1802 | 900 | 1802 | 900 | Request for expedited examination of a design application | |

Other fee (specify)

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($)

## SUBMITTED BY

(Complete *(if applicable)*)

| | | | |
|---|---|---|---|
| Name (Print/Type) | Dr Elan Ziv MD | Registration No. (Attorney/Agent) | Telephone +97237369261 |
| Signature | | Date | March 14, 2004 |

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

*If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.*

# A FLEXIBLE MID-URETHRAL SUPPORT DEVICE FOR THE TREATMENT AND PREVENTION OF URINARY INCONTINENCE IN FEMALES

The present invention relates generally to the field of treatment of urinary incontinence in female patients. More specifically, the present invention relates to a disposable device for use in the treatment of urinary incontinence in women. The invention describes a vaginal disposable device which is inserted and removed in a no-self-touch technique, by the patient herself, using a disposable applicator.

**Inventor**: Dr Elan Ziv, MD OBGYN, Urogynecologist

## *Background of the Invention*

Urinary incontinence is a widespread problem among females. It is estimated that up to 50% of women occasionally leak urine involuntarily, and that approximately 25% of woman will seek medical advice at some point in order to deal with the problem. Stress incontinence, the most common type of urinary incontinence, refers to the involuntary loss of urine resulting from abdominal pressure rise, occurring during exercise, coughing, sneezing, laughing, etc. When stress incontinence occurs, it is usually the result of the abnormal descent of the urethra and bladder neck below the level of the pelvic floor. While many different factors may contribute to the development of stress incontinence, it is most prevalent among women ages 35-65 and those who have had multiple vaginal deliveries. Stress incontinence is both aggravating and unpleasant for women, and it can also be embarrassing. Many women wear sanitary pads or diapers in order to deal with incontinence, though this is not a real solution to the problem and it can be very inconvenient and unreliable. Surgical treatment may involve securing the paraurethal tissues to the periosteum of the pubic bone or the rectus facia in order to elevate the bladder neck above the pelvic floor and thereby distribute pressure equally to the bladder, the bladder neck, and the mid-urethra. Recently, a procedure known as "TVT" ("Tension Free Vaginal Tape") was developed, in which a mesh tape is implanted underneath mid-urethra, creating a hammock on which the urethra may kink during physical effort.

However, surgery is only suitable for severe cases, and the majority of women experiencing incontinence do not need surgical solutions.

One modality of non-surgical treatment involves the use of devices that are inserted into the vagina, either by a medical practitioner or by the woman herself. Most devices are designed to apply pressure against the bladder neck so as to inhibit or completely block the flow of urine through the urethra. A variety of such devices are known in the art. For example, refer to U.S. Patent No. 5,618,256 to Reimer, entitled, "Device for Arrangement in the Vagina for Prevention of Involuntary Urination with Females and an Applicator for use in Insertion of the Device;" U.S. Patent No. 5,785,640 to Kresch, entitled "Method for Treating Female Incontinence;" U.S. Patent No. 4,920,986 to Biswas, entitled, "Urinary Incontinence Device;" U.S. Patent 5,417,226 to Juma, entitled, "Female Anti-Incontinence Device;" U.S. Patent No. 5,386,836 to Biswas, entitled, "Urinary Incontinence Device;" and U.S. Patent No. 5,007,894 to Enhorning, entitled, "Female Incontinence Device."

The existing non-surgical incontinence devices suffer from numerous drawbacks:

- A number of devices are constructed so as to completely block the urethra and thus they need to be removed or collapsed in order to allow the woman to urinate, an inconvenience for the woman wearing the device.
- To overcome this drawback, vaginal devices have been developed having specialized shapes that do not completely block the bladder neck. These devices tend to be large, uncomfortable, and intrusive. They also tend to cause irritation or soreness to the vagina.
- Such devices are expensive to manufacture, and therefore, they are designed to be re-usable and/or to remain in the vagina for an extended period of time. Such devices are normally made from large bodies of resilient material, such as plastic or hard rubber, in order to preserve their functioning for the required amount of time.
- Most devices known in the art also tend to be difficult or painful to insert and/or remove. In order to correctly inhibit urine flow, the device needs to be properly positioned in the vaginal canal. As stated previously, a doctor may be required to properly position the device.

- In cases where a doctor has to insert the device, the device is adapted for remaining in the vagina for a prolonged period of time. When positioned in the vagina for an extended period of the time, the device may cause vaginal infections, necrosis, or bleeding.
- The device may block or inhibit the flow of normal body secretions through the vagina, and may cause inflammation of the vagina and a foul-smelling discharge.
- In cases where the device is designed to be inserted by the woman herself, the device often has to be removed, cleaned, and then re-inserted after a predetermined number of hours.

All vaginal devices so far described or marketed have at least one of the limiting features described above. No vaginal device for controlling urinary incontinence has so far been successfully marketed and used by the woman herself. There is a need for a device for controlling involuntary urination that is disposable, easy and comfortable for a woman to use, that works effectively and reliably, and that is completely sanitary and hygienic.

***The Invention***

The present invention provides a device for the treatment of urinary incontinence females. The device of the present invention is adapted to be disposable, worn only for a maximum of 16 hours and then discarded and replaced with a new device (if needed). The device of the present invention is simple and easy to use, and is inserted effortlessly in the same user-friendly and familiar manner that a tampon is inserted into the vagina during menstruation. As opposed to large and intrusive devices of the prior art, the device of the present invention is comfortable, and, once inserted, the woman need not think about it again until it is removed.

When involuntary urination occurs, it is usually the result of the abnormal descent of the bladder neck and the urethra into a low position, away from the intra-abdominal pressure system. This "hypermobility" is the result of some injury to the support mechanism which normally keeps the urethra and the bladder neck in a raised position, along the backside of the pubic bone. The lowering of the bladder neck and the urethra that occur, for example, when a woman coughs, sneezes, or laughs, causing involuntary leakage of urine. The device of the present invention is designed so as to provide a "cradle" or shelf-like support to the urethra whenever the urethra descends momentarily, so as to prevent the leakage of urine. The device does not put pressure against the urethra or the bladder neck, but only provides support when there is a rise in abdominal pressure.

The present invention relates to a disposable device for the prevention of involuntary urination in females, adapted for being inserted into the vagina, comprising;

(a) an internal support structure

(b) a cover covering said internal support structure and comprised of a flexible material, and;

(c) an applicator coupled to the internal support structure and the cover for facilitating insertion of the device into the vagina;

The main device and the cover are adapted for forming a cradle support for the mid-urethra following insertion of the device into the vagina so as to prevent involuntary urination while allowing for voluntary urination.

The invention will now be described with reference to accompanying drawings:

FIG. 1A is a side view of the internal support structure.

FIG. 1B is a top view of the internal support structure

FIG. 1C is a bottom view of the internal support structure

FIG. 2A is a perspective view of the covering

FIG. 2B is a perspective view of the main device inside the covering.

FIG. 3 is a perspective view of the applicator.

FIG. 4 is a sectional view of the invention within the applicator

FIG.5 is a side view of the female pelvis.

FIG.6 is another embodiment of the device with different shapes and curves of the arms.

The core of the device is a one prolonged embodiment (FIG 1A) which has three distinct parts:

1. A top section (12) which serves as the "anchoring" element, for stabilizing the device within the vagina,
2. A bottom section (14) which serves as the "supporting" element, generating mid-urethral support,

Each element of the device (FIG 1A+B+C) has 4 flexible arms. These arms of the anchoring element (12), force the device to remain in situ within the vagina, unable to move inwards or outwards, or to rotate. This occurs as a result of the special tendency of vaginal walls to collapse and form an occluded lumen. The flexible arms of the device cause "tenting" of the walls on top of them with resultant sagging of the walls around the intermediate section, thereby stabilizing the device. The arms of the supporting element (14) cause elevation of the tissues around mid-urethra, acting as a hammock. This hammock supports mid-urethra in a tension free manner, much like the TVT operation.

The device is introduced into the cover (FIG 2).

Another embodiment of the device, with different shapes and curves of the arms is shown in FIG 6.

The cover (FIG 2A) is made of a flexible smooth mesh material (16) designed as small sack with a string (18). FIG 2B shows the device (20) within the tightly closed mesh cover (22). The cover allows for:

- Reduction of the friction between vagina and the device during insertion & removal.
- Reduction of the friction between the applicator and the device during insertion.
- Pulling the string causes straightening of the cover, straightening of the vaginal walls, allowing for an easy and smooth removal of the device from the vagina.
- Pulling the string causes the arms to fold slightly towards the midline, thereby reducing its size, allowing for an easy and smooth removal of the device from the vagina.
- The mesh of the cover, being stretched between the arms of the device, also serve as a hammock. In a woman who leaks urine during a stressful event (when abdominal pressure rises during coughing, sneezing, etc.), the urethra sags down but meets the hammock in its mid part. That also causes an elevation of the intra urethral pressure with resultant urinary continence.

The applicator serves for insertion of the device into the vagina (FIG 3), as is done when inserting a regular menstrual tampon. The device is kept within the wider part (26) that is inserted into the vagina. When pushing the plunger (28), the device is pushed through the flower like opening (24), allowing for its immediate action once the applicator is removed from the vagina. The string (32) is visible, protruding out of the opening of the plunger (30).

When the device is still within the applicator (FIG 4), its flexible arms (34) converge towards the midline, allowing for the small dimensions and its insertion via a small diameter applicator. After insertion (FIG 5), the flexible arms of the device gain their pre-intended tension, enlarge the diameter of the device (46) within the vagina (48), anchoring itself under the bladder (40) between the uterine cervix (36) and the pubic bone (38), supporting mid-urethra (42). The string protrudes out of the vaginal introitus (44), as with the regular menstrual tampon, allowing for removal.

The invention has in its basic concept the following features:

- Being a disposable device.
- Insertion of the device is always with an applicator.
- Easy & comfortable insertion and removal.
- Being comfortable to wear.
- Being hygiene & odorless
- Being a familiar procedure to most female patients – as inserting a menstrual tampon.
- Being inserted by the patient herself, in a no-self-touch technique, with a disposable inserter.
- Being removed by the patient herself, in a no-self-touch technique, with the device collapsing and becoming of small size for painless removal.
- Being of high availability, easy to get everywhere, sold as an Over the Counter (OTC) device.
- Being of low cost.
- Having complete confidentiality, as with the use of menstrual tampons.
- Having the ability to be removed instantly when needed.
- No blockage of vaginal discharge.
- Wide range of diameters

**Alternative embodiments of the invention.**

- It may be manufactured in different sizes
- It may be made of many flexible materials, such as silicone, polyurethane, etc.
- It can have more or less than 4 arms.
- The angle between the arms may be changed.
- Shape and curves of the arms may vary

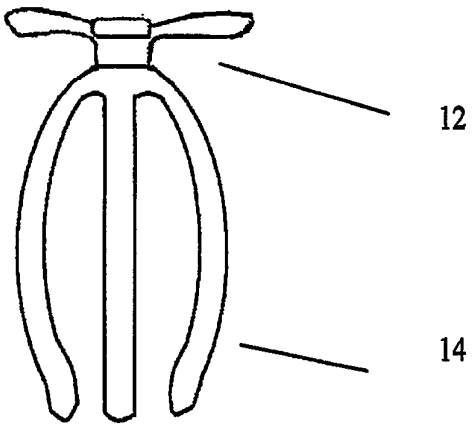


FIG. 1A

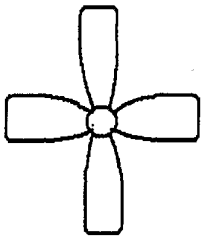

FIG. 1C

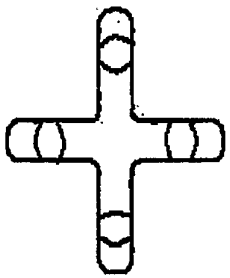

FIG. 1B

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD, OBGYN, Urogynecologist

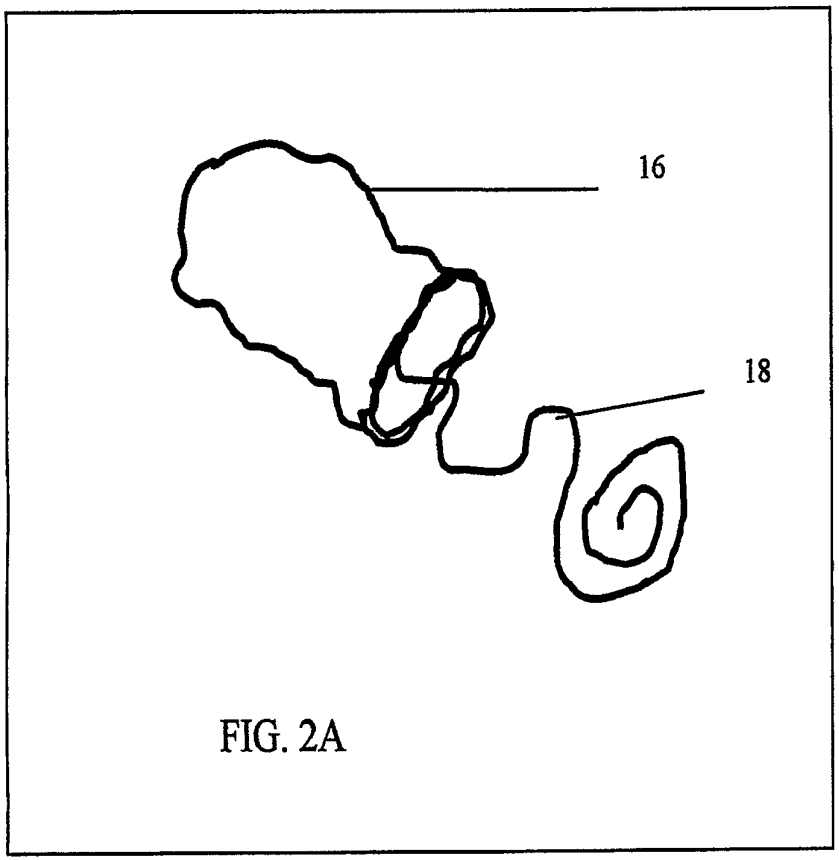


FIG. 2A

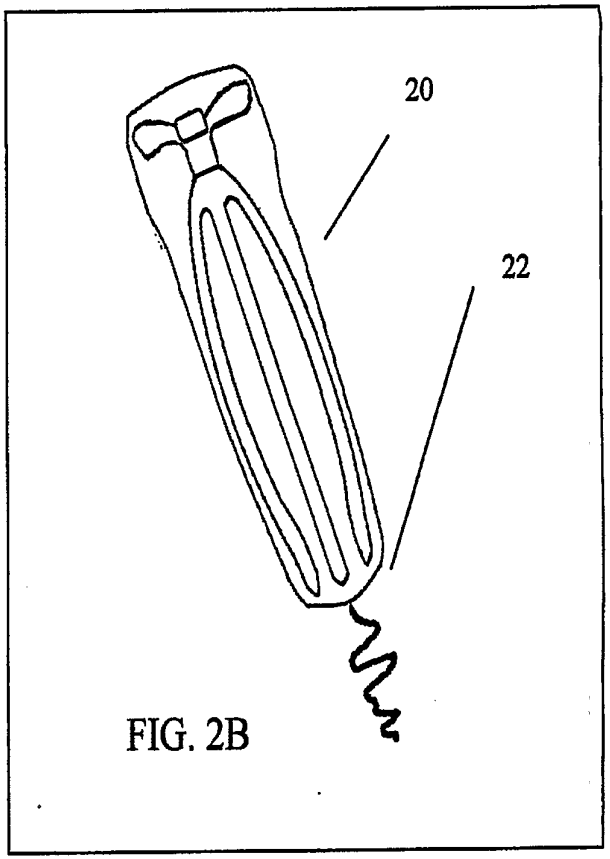


FIG. 2B

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD, OBGYN, Urogynecologist

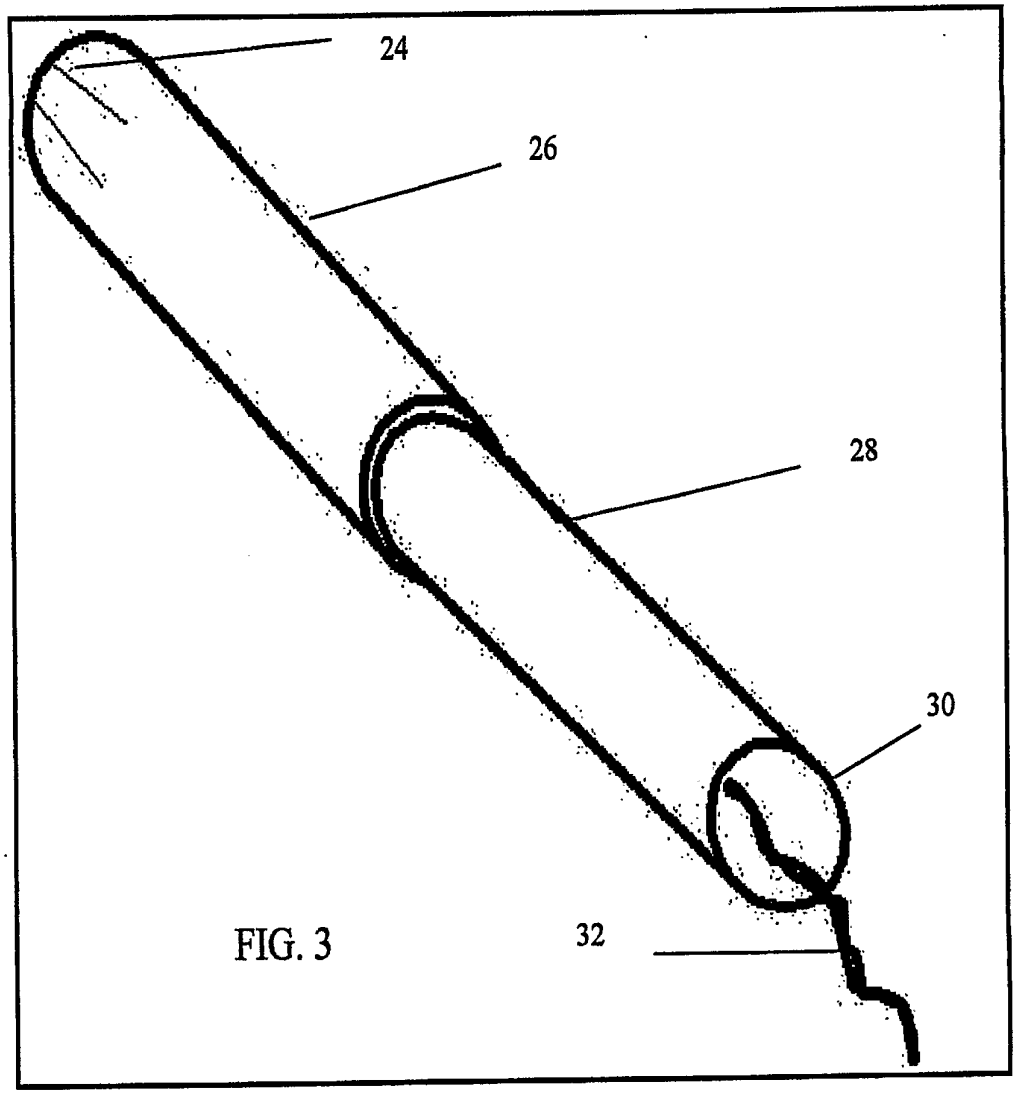


FIG. 3

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD, OBGYN, Urogynecologist

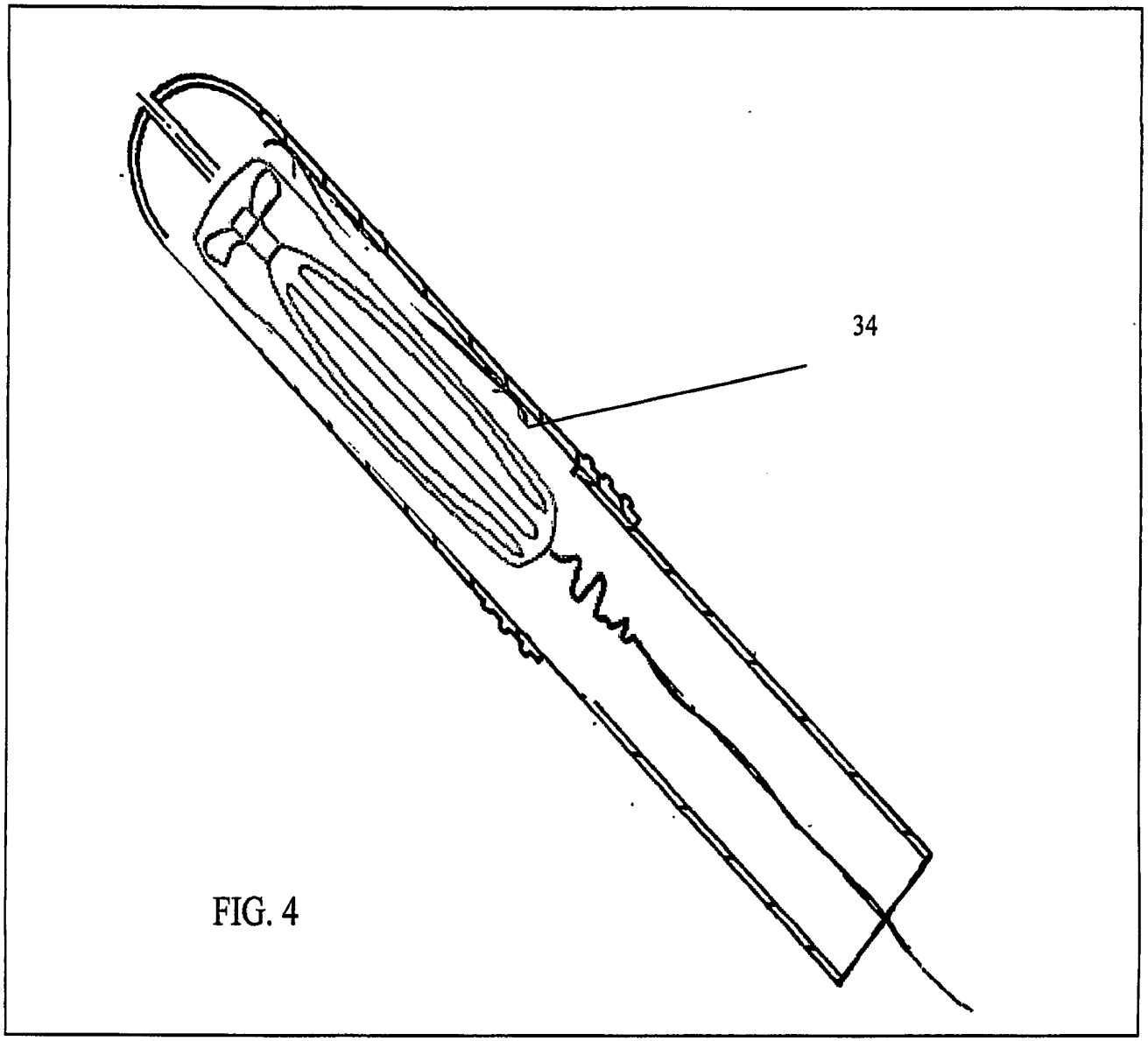


FIG. 4

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD, OBGYN, Urogynecologist

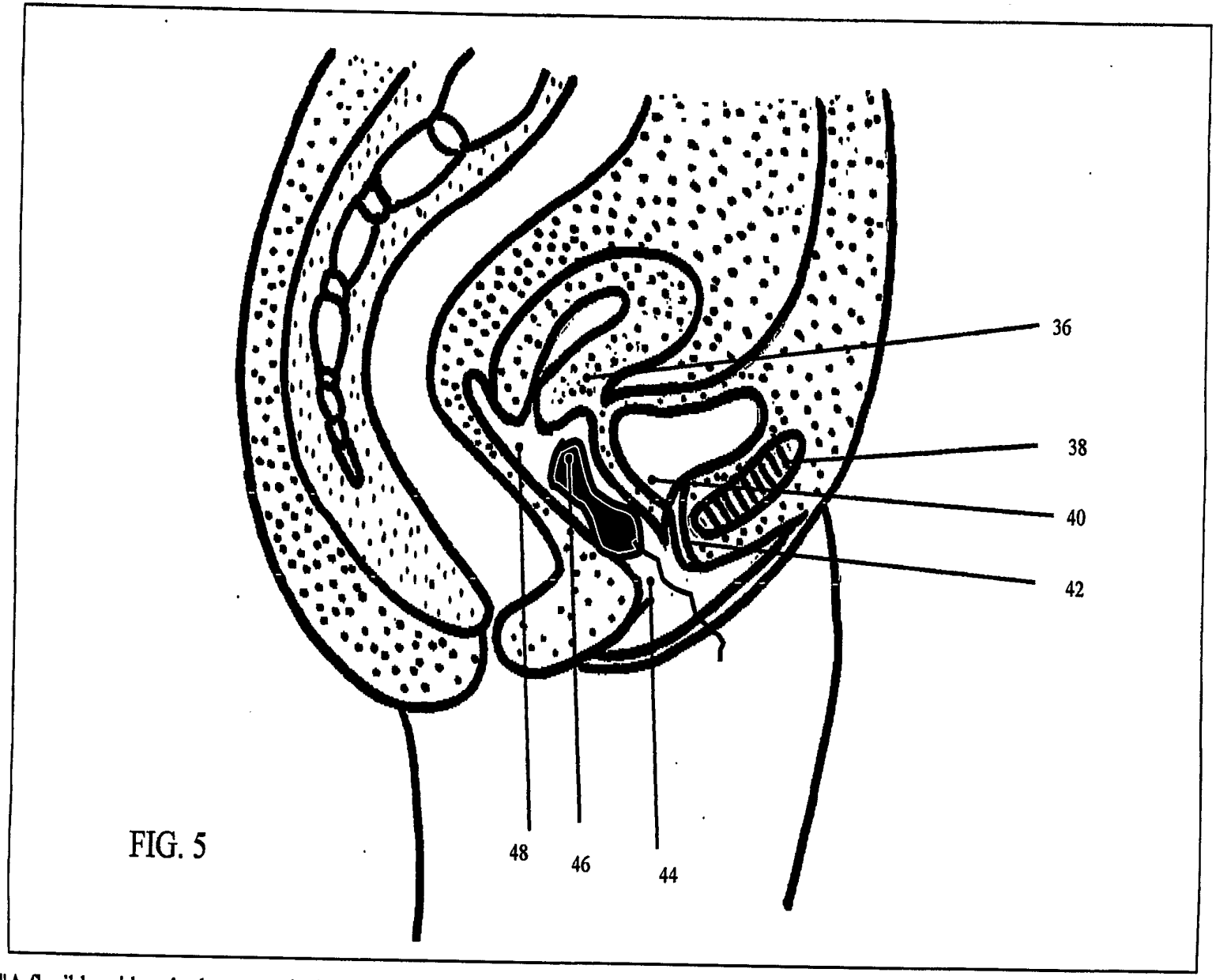


FIG. 5

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD, OBGYN, Urogynecologist

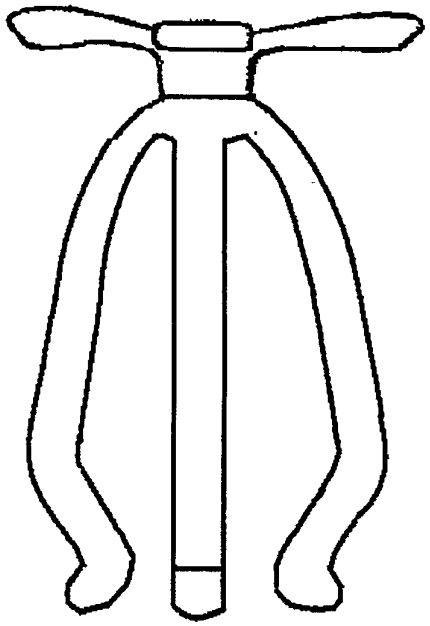

FIG. 6

"A flexible midurethral support device for treatment & prevention of female urinary incontinence"
Dr Elan Ziv, MD, OBGYN, Urogynecologist